

Question: Are APRNs authorized to order or prescribe monoclonal antibody infusions for the treatment of COVID-19? Is this considered off-label use and prohibited by Board Rule?

Response: Off label drug use is commonly considered to be the ordering or prescribing of a drug for an indication that differs from the indication for which the drug is approved by the US Food and Drug Administration (FDA). Off label use can also refer to the use of a drug in a different dosage or different form than was approved by the FDA or for a different patient population (Wittich, et al., 2012). Board Rules do not prohibit ordering and prescribing drugs off-label provided the decision to prescribe that drug is supported by evidence based research and is within the current standard of care for treatment of the disease or condition. Off-label prescribing by APRNs is specifically addressed in [Board Rule 222.4\(f\)](#).

With regard to the question about APRNs ordering or prescribing monoclonal antibodies for the treatment of COVID-19, it is necessary to consider that there are monoclonal antibody products that have emergency use authorization from the FDA. Information regarding these products may be further reviewed in this [discussion from the National Institutes of Health \(NIH\)](#). While the information provided by the NIH is clear that emergency use authorization is not the same as full FDA approval, it is also clear that the FDA has acknowledged the benefit of certain monoclonal antibody products and authorized their use for treating COVID-19 in certain situations based on the evidence thus far. Given the emergency use authorization and the current standards for treatment of COVID-19 from the [NIH](#) and [Infectious Diseases Society of America](#), it is reasonable to consider that this is the intended use of these monoclonal antibodies. Therefore, the use of monoclonal antibodies with emergency use authorization for the treatment of COVID-19 is not viewed in the same way as the off-label use of FDA approved drugs.

An APRN may order or prescribe monoclonal antibody treatments that have received emergency use authorization for COVID-19 patients when it is within the current standard of care to do so provided it is within the scope of the role and population focus for which the APRN has been licensed. The APRN must have the appropriate physician delegation [see [Board Rule 221.13\(d\)](#)] and prescriptive authority agreement ([Board Rule 222.5](#)) or facility-based protocol ([Board Rule 222.6](#)) in place prior to engaging in this practice.

It is important to recognize that the standard of care for the treatment of COVID-19 is changing rapidly as research and clinical trials continue to reveal new information about this virus, its variants, and its responses to pharmacological therapies and treatments. Thus, it is important to emphasize that each APRN has a duty to ensure that the drugs and treatments ordered or prescribed are within the current standard of care.

References:

Wittich, C. M., Burkle, C. M., & Lanier, W. L. (2012). Ten common questions (and their answers) about off-label drug use. *Mayo Clinic Proceedings*, 87(10), 982–990.
<https://doi.org/10.1016/j.mayocp.2012.04.017>